United States Patent [19]

Shturman et al.

[11] **Patent Number:** 4,788,975

[45] **Date of Patent:** Dec. 6, 1988

[54] **CONTROL SYSTEM AND METHOD FOR IMPROVED LASER ANGIOPLASTY**

[75] Inventors: Leonid Shturman, Minnetonka; Steven L. Jensen, Coon Rapids, both of Minn.

[73] Assignee: Medilase, Inc., Minneapolis, Minn.

[21] Appl. No.: 117,666

[22] Filed: Nov. 5, 1987

[51] Int. Cl.⁴ A61B 17/36
[52] U.S. Cl. 128/303.1; 211/121.61
[58] Field of Search .... 128/6, 303.1, 395-398, 128/419 P, 419 R; 219/121.61, 121.62

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,418,688	12/1983	Loeb	128/6
4,448,188	5/1984	Loeb	128/6
4,538,613	9/1985	Rosenberg	128/395
4,576,177	3/1986	Webster	128/303.1
4,587,972	5/1986	Morantte	128/303.1
4,641,650	2/1987	Mok	128/303.1
4,641,912	2/1987	Goldenberg	128/6
4,648,892	3/1987	Kittrell et al.	128/303.1
4,654,024	3/1987	Critteren et al.	604/49
4,669,467	6/1987	Willett et al.	128/303.1
4,672,963	1/1987	Barkey	128/303.1
4,682,594	7/1987	Mok	128/303.1
4,706,656	11/1987	Kuboto	128/6
4,718,417	1/1988	Kittrell et al.	128/303.1
4,719,912	1/1988	Weinberg	128/303.1

FOREIGN PATENT DOCUMENTS

8606642 11/1986 World Int. Prop. O. .

OTHER PUBLICATIONS

Continuous On-Line Assessment of Coronary Angioplasty with a Doppler Tipped Balloon Dilation Catheter by Sibley, Bulle, Baxley, Dean and Whitlow, 1986.

Fiberoptic Laser-Induced Fluorescence Detection of Atherosclertosis and Plaque Ablation: Potential for Laser Angioplasty Guidance, by Deckelbaum, Stetz, Lam, Clubb, Cutruzola, Cabin and Long, 1986.

Detection of Atherosclerotic Plaque and Characterization or Arterial Wall Structure by Laser Induced Florescence by Sartori, Bossaler, Weilbacher, Henry and Roberts, 1986.

Laser Induced Plaque Artherolysis with Tetracycline by Abela, Barbieu, Roxey and Conti., 1986.

Primary Examiner—Max Hindenburg
Attorney, Agent, or Firm—Vidas & Arrett

[57] **ABSTRACT**

A control system and method for laser angioplasty or laser ablation or welding of tissue in general, in which firing of a laser catheter is correlated with movement of a vessel or other body chamber carrying the laser catheter, whereby the laser is fired only during those times its fiberoptic-delivered beam is aimed at plaque or other target in the vessel or chamber.
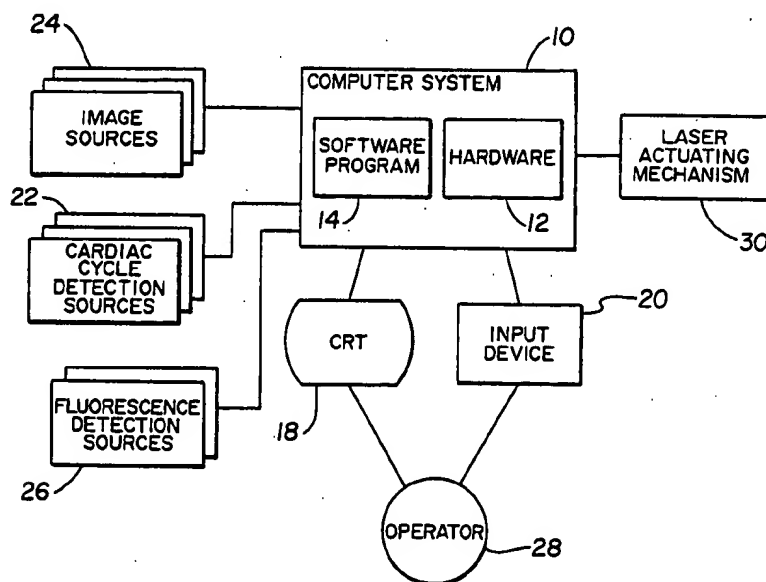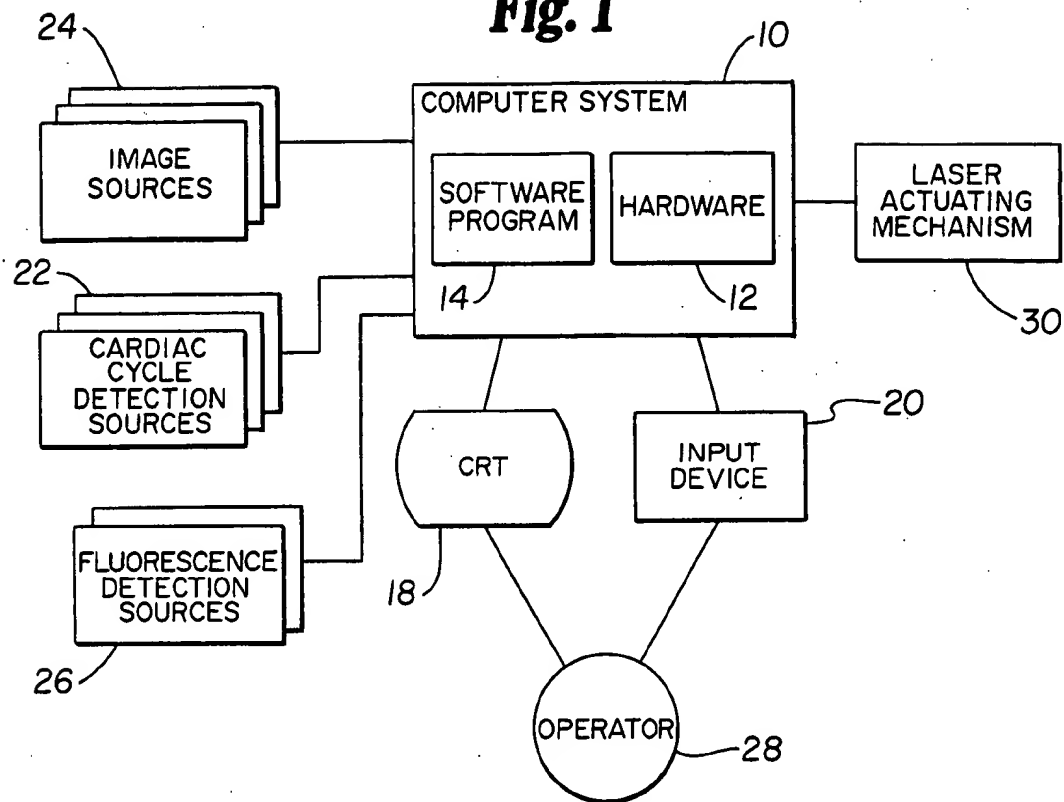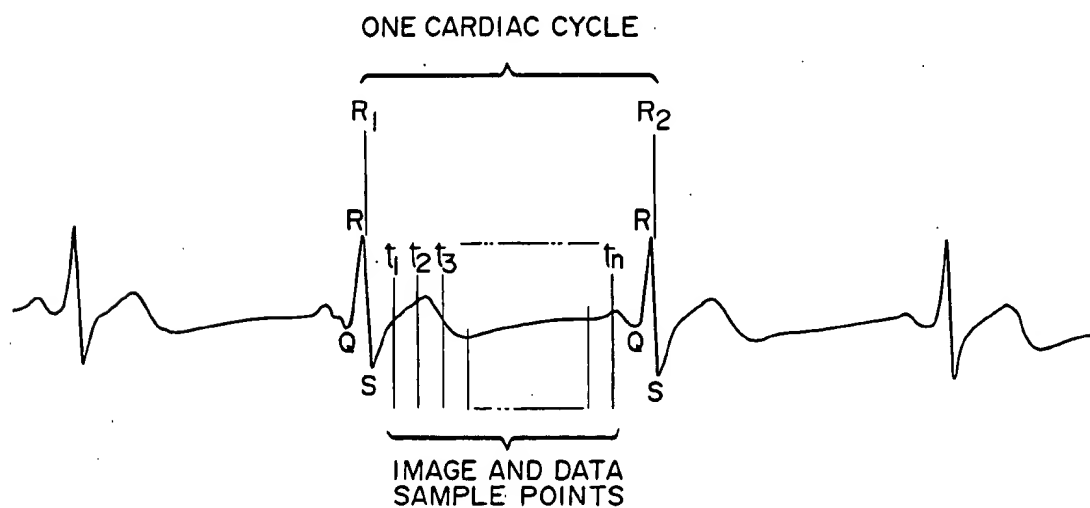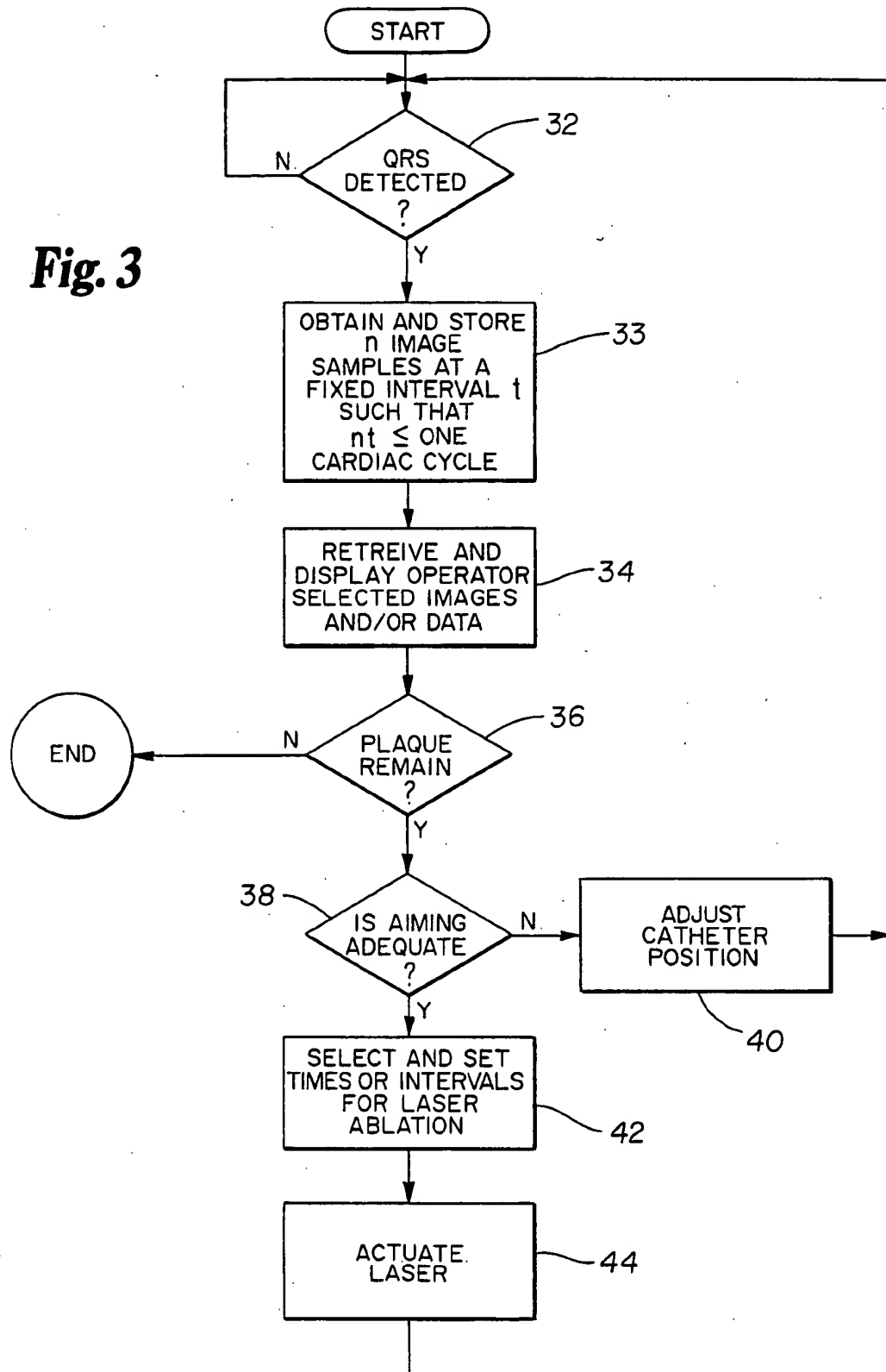
28 Claims, 2 Drawing Sheets

Fig. 1

IMAGE SOURCES — 24

CARDIAC CYCLE DETECTION SOURCES — 22

FLUORESCENCE DETECTION SOURCES — 26

COMPUTER SYSTEM — 10

SOFTWARE PROGRAM — 14

HARDWARE — 12

LASER ACTUATING MECHANISM — 30

CRT — 18

INPUT DEVICE — 20

OPERATOR — 28

Fig. 2

ONE CARDIAC CYCLE

R_1 R_2

R t_1 t_2 t_3 t_n R

Q   Q

S   S

IMAGE AND DATA SAMPLE POINTS

Fig. 3

START

N ← QRS DETECTED ? ─32

Y ↓

OBTAIN AND STORE n IMAGE SAMPLES AT A FIXED INTERVAL t SUCH THAT nt ≤ ONE CARDIAC CYCLE ─33

↓

RETREIVE AND DISPLAY OPERATOR SELECTED IMAGES AND/OR DATA ─34

↓

PLAQUE REMAIN ? ─36

N → END

Y ↓

38─ IS AIMING ADEQUATE ? → N → ADJUST CATHETER POSITION ─40

Y ↓

SELECT AND SET TIMES OR INTERVALS FOR LASER ABLATION ─42

↓

ACTUATE LASER ─44

1

CONTROL SYSTEM AND METHOD FOR IMPROVED LASER ANGIOPLASTY

BACKGROUND OF THE INVENTION

The invention relates specifically to laser angioplasty and to improved methods and apparatus therefor. With this in mind, the invention will be specifically described with reference to laser systems and methods for ablating plaque, although it has broader applicability. For example, it is applicable to the so called hot probe laser approach as described in U.S. Pat. No. 4,650,024, entitled "Thermorecanalization Catheter and Method for Use", issued March 31, 1987. In its broader sense the invention relates to any medical treatment systems and method for effecting treatment to selected sites in the body in which cyclic or repetitive movement is involved.

The aiming of laser energy accurately at atherosclerotic plaque within a vessel, such as a coronary artery, is negatively affected by the continuous movement of the vessel. This movement is associated with cardiac contractions, hence relates to phases of the cardiac cycle. As a result of such movement a laser catheter positioned within a vessel also undergoes relative movement and may at times be aimed at plaque and at other times aimed at normal vessel wall.

Mechanical damage to vessels, including wall perforation, continues to be a major problem with laser angioplasty. The aiming of laser energy (delivered via a fiberoptic delivery system) is a major task. The continuous motion of the vessel wall significantly complicates aiming and delivering of laser energy accurately to the atherosclerotic plaque. The prior art has treated the movement of coronary arteries and other vessels as a problem rather than attempting to take advantage of the repetitive nature of the movement of coronary arteries as displayed from one cardiac cycle to another.

The present invention relates to a control system for timing the delivery of laser energy such that it accurately impinges on plaque or other intended target area.

SUMMARY OF THE INVENTION

According to this invention the repetitive motion of the walls of the ventricles (or heart chambers in general) and the motion of associated vessels during heart cycles is taken advantage of and delivery of laser energy for ablation of the plaque (or other type of obstruction or target) is provided only during specific, predetermined times or time intervals during a cardiac cycle or cycles. Thus, in accordance with this invention one takes into account the repetitive nature of the movement of the vessel carrying the laser catheter and uses the repetitive nature of the movement for timing the firing of the laser only when the laser beam (delivered via fiberoptic-based catheter) and the plaque or other obstruction or target are coincident i.e., at times when accurate aiming exists.

In accomplishing this it is necessary to identify, during a number of consecutive cardiac cycles, those times during the cycle when the laser catheter is aimed at the target area and not at normal vessel wall. It can be seen that during certain times of such a cycle repetitive movement of the vessel will bring the atherosclerotic lesion i.e., a target area into a position where the laser energy will impinge on it. Therefore, the laser energy delivery during such time or time intervals will be safer and will significantly diminish probability of vessel wall perforation. Consequently, the movement of the vessel

2

is no longer treated as a problem but rather the motion is taken advantage of by timing its cyclic movement and selecting or defining those times or time intervals when the laser energy is coincident with respect to the targeted area, for firing the laser.

More specifically, with the proposed invention, after initially positioning and aiming the distal end of fiberoptic-based laser catheter at a target area such as plaque or some other obstruction or target area within the vessel, the entire cardiac cycle is artificially divided into a number of fixed time intervals, as determined by the physician-operator. For the purpose of establishing a cardiac cycle, the QRS complex from an electrocardiogram may be used to establish the beginning and end points of a repetitive cycle to be used. During a plurality of times within such a cycle an image or signal indicative of the position of the distal end of a laser catheter, relative to the target, may be obtained during each of those times. Such an image or signal (more than one may be involved and used) are stored, preferably in an electronic storage media such as a digital memory or video tape, for later review and use.

Images may include fluoroscopic or angiographic (both radiographic) images and or images from a fiberoptic angioscope. Signals may be also obtained from an ultrasound transducer mounted at the distal tip of a laser catheter. Also, laser induced fluorescence signals (plaque and normal vessel walls fluoresce differently in response to a laser radiation) may be used alone or simultaneously with other signals and/or images throughout any predetermined number of cardiac cycles.

All such data may be stored electronically for subsequent review by a physician-operator of the system. After sufficient data has been accumulated in the storage medium the images and signals may be reviewed frame by frame. It is preferable to review at the same time all images and signals which were obtained at the same time in the cycle. Window type presentation of multiple images and signals on one screen is also preferable. The review is not done in real time but at a speed convenient for the physician-operator. The review of the collected data allows the physician-operator to determine those times of the cycle during which the laser catheter is accurately aimed at the target area. Through the use of a microcomputer or other computer means, appropriate programming may then be placed into operation to control the firing of the laser catheter for delivery of laser radiation during upcoming cardiac cycles and only during those times or time intervals when it has been determined that the laser beam is aimed directly at or coincident with the target area.

In a simple system only one image or signal may be utilized to verify aiming. However, in a more sophisticated system, wherein one or more images and/or signals are stored for review, all of the images and signals which have been obtained simultaneously from several sources during given times of a cycle may be used to confirm the accurate or inaccurate aiming of the laser catheter at the target area.

Agreement concerning aiming between different sources of data confirms for the physician-operator those time intervals of the cycle when it is safe to activate the laser for ablating the target area. Trains of ablative laser pulses throughout these safe times or time intervals, which may be one time or time interval of one cycle or several cycles or several times or time intervals

3

extending over a number of cycles may be utilized. Such a system of aiming verification will provide improved operation of a laser angioplasty system and is most preferred.

As indicated above, the QRS complex of an ECG may be used for establishing a cycle representative of the vessel movement and is preferred. However, other sources for establishing representative cycles may be used such as the blood pressure in the aorta, blood flow in the cardiac ventricle or aorta or an artificial pacing cycle may be established with the pacing pulse used as a reference.

DESCRIPTION OF THE DRAWING

The present invention will be apparent from the detailed description provided herein taken in conjunction with the accompanying drawing in which:

FIG. 1 is a block diagram, showing the construction of a hardware embodiment of the invention;

FIG. 2 is a representation of an electrocardiogram showing deflections resulting from atrial and ventricular electrical activity. The QRS complex is due to excitation of the ventricle and is used according to the invention to establish a repeatable time cycle, and

FIG. 3 is a flowchart showing the operation of the overall system.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In its preferred form, this invention will be practiced in combination with the laser catheter described in copending application Ser. No. 066,937, entitled Laser Angioplasty and filed June 25, 1987. That application is assigned to the same assignee as in this application. Its contents are incorporated herein by reference. The following description of the subject invention refers particularly to an overall system and method and not to any particular catheter construction.

FIG. 1 shows an embodiment of the invention. In the Figure a computer system 10 includes computer hardware 12 and software program means 14. Hardware 12 includes storage means (not shown). Also connected to computer 10 are a display CRT 18 and a user input device such as a keyboard, mouse, light pen or joy stick arrangement or others 20. The storage means is constructed and arranged such that signals, such as electrocardiogram data including QRS complex time points or other cardiac cycle time points, may be used to trigger acquisition and/or storage of images and other data concerning the relative positions of the laser catheter and a target area in a vessel or chamber carrying the laser catheter. The images and other data may be generated by one or more various means 24 and 26 and are introduced into the storage means hardware.

Storage and digital image subsequent processing may be accomplished by a system such as the Trapix 5500 digital image processor available from Recognition Concepts Inc., 341 Skiway, P.O. Box 8510, Incline Village, Nev., 89450. Another imaging system known as View 2000 is available from a company known as Virtual Imaging, 725 Kieffer Rd., Sunnyvale, Calif. 94086.

The various positional data means indicated at 24 and 26 may take various forms. For example, one of these may take the form of an imaging system in which an image showing the relative positions of the laser catheter and the target area may be generated angiographically, including utilization of Digital subtraction Angioplasty (DSA) if necessary, or angioscopically and

4

stored in the storage means for display on CRT 18. From such images one can determine if the laser catheter is accurately aimed at selected target area.

In addition to or in lieu of actual images, various sensing arrangements which generate a signal indicative of a positional relationship of the laser vis-a-vis the target area may also be used with the present invention. As already indicated, the fluorescence effect exhibited by plaque is different than the fluorescence effect exhibited by a vessel wall, the florescence being in response to impinging low level radiation. See the abstract of a presentation entitled *Fiberoptic Laser-Induced Fluorescence Detection of Atherosclerosis and Plaque Ablation; Potential for Laser Angioplasty Guidance*". by Decklebaum, Stetz, Lam, Clubb, Cutruzzola, Cabin and Long given at the American Heart Association in Dallas, Tex. and abstracted as paper #27 (II-7) in the Part 2, Volume 74, Number 4, October 1986, Manograph Number 124, Circulation Supplements, Abstracts from the 59th Scientific Sessons, American Heart Association. Also from the same sessions, see Abstract #25 (II-7) entitled *"Detection of Atherosclerotic Places and Characterization or Arterial wall Structure by Laser Induced Fluorescence"* by Sartori; Bossaler, Weilbacher, Henry and Roberts and see Abstract #26 (II-7) entitled *"Laser Induced Placue Atherolvsis with Tetracycline"* by Abela, Barbieu, Roxey and Conti. In accordance with this invention a sensing means responsive to such flourescence may be included in the system, the particular type of the fluorescence being indicative of when the catheter is on target and when it is not.

Likewise, a data signal may be generated by means of an ultrasound tranducer which may be mounted on the distal end of the laser catheter. See the abstract of a presentation entitled *"Continuous On-Line Assessment of Coronary Angioplasty with a Doppler Tipped Balloon Dilatation Catheter"* by Sibley, Bulle, Baxley, Dean and Whitlow given at the same Scientific Sessions above-identified and abstracted as #1828 (II-459). Such data may also be stored for later review and use. Ultrasound image or images can be reconstructed from such signals or data.

With constructions such as those described above, after initially positioning a laser catheter in a vessel and aiming it at a target area, positional images and data and/or signals as described above generated by various modalities are obtained at predetermined times throughout any desired number of cardiac cycles. Such a cardiac cycle is shown in the electrocardiogram of FIG. 2 wherein the repeating cycle is defined by time between QRS complex R_1-R_2 of an ECG. In the cycle illustrated, a plurality of time points $t_1 \ldots t_n$ represent the times during which the images and/or signals are generated to determine whether the laser catheter is accurately aimed at the target area or not. Simultaneous collection of various positional images, data and/or signal by various modalities (whether carried by the catheter or independently operative means) such as 24 and 26 may be taken at each point of time $t_l \ldots t_n$ for storage (on electronic memory means such as video tape or optical disc, etc.). Then, all of these images and data may be recalled and reviewed frame by frame preferably with simultanteous review of images and data from different imaging and data or signal sources obtained at the same time in the cardiac cycle.

This review is not done in real time but at a speed convenient for the physician-operator 28. Any number of cardiac cycles and number of times or time points per

5

cycle may be selected by the physician-operator. The review of this data allows the physician-operator to determine those time or time intervals of the cycle during which the laser catheter is reliably and consistently aimed at the target area.

Then and only then, computerized control of the laser actuating mechanism 30 may be set through input device 20 to energize or trigger the laser or allow the laser beam to enter the shooting optical fiber of the laser catheter during those times or time intervals of the upcoming cycle when the catheter is reliably aimed at the target area.

If any abnormal pattern of cardiac activity is observed by the physician-operator or identified by computerized control system, the operator or the computerized control system is arranged to automatically block delivery of ablating laser radiation.

FIG. 3 shows a program flow chart for the operations performed by the hardware shown in FIG. 1. FIG. 3 represents the various steps involved in selecting times during which to actuate the laser or otherwise allow laser radiation to impinge on a target area. The first step in this process occurs at 32 when the QRS time points are generated. 32 represents the step in which the time period cycle between two consecutive QRS complex points R_1-R_2 are determined. The next step is indicated at 33 in which the time period R_1-R_2 is divided into a number of times t and n number of images or data signals are obtained and stored from one or more instruments which the physician-operator selects for each of the time intervals t_1 to t_n during one cycle. During next step 34, the images or data readings obtained in step 33 are displayed on the CRT in operator selected format. Step 36 indicates the point at which it is determined if plaque or other suitable target is present. Step 38 indicates a decision point in which the operator must decide whether the laser is accurately aimed during one or more of the times or time intervals. If the laser is not aimed at the plaque during one or more of the time intervals, step 40 is executed, which involves adjusting the catheter position and returning steps 32–38. If the operator determines that the laser is aimed at plaque or the like during one or more time intervals, step 42 is performed. Step 42 consists of the operator selecting the particular time or time interval during which to fire the laser in an upcoming cycle or cycles and inputting this time or time intervals and the number of cycles into the computer. The last step indicated at 44 is triggering the laser actuation mechanism which either activates the laser itself or allows the laser beam to enter the laser catheter.

From the foregoing description it will be seen in accordance with this invention that the safe firing of a laser catheter in an angioplasty system may be accomplished. Preferably this is done by using various modalities associated with the catheter and independent of it to generate positional data and confirm the adequacy of the aiming or the need to adjust same.

What is claimed is:

1. In combination with a laser angioplasty system in which a laser catheter is positioned within a moving vessel and oriented to impinge radiation upon a selected target site within the vessel, the improvement comprising:

means for defining a cycle representative of repetitive vessel movement;

6

means for defining the position of the laser catheter relative to the selected target site during various times of the cycle, and

means for activating the laser catheter at a selected time or times to impinge laser radiation on the target site during an upcoming cycle or cycles.

2. The combination of Claim 1 in which the means for defining a cycle representative of vessel movement defines an aspect of the cardiac cycle.

3. The combination of claim 1 in which the vessel is a coronary artery and the means for defining a cycle representative of vessel movement defines an characteristic relative to the coronary artery.

4. The combination of claim 1 wherein the means for defining the cycle includes electrocardiographic data.

5. The combination of claim 4 wherein the cycle is defined by the QRS complex.

6. The combination of claim 1 wherein the means for defining the position of the laser catheter includes at least one imaging system.

7. In combination with a laser angioplasty system for the delivery of laser energy to atherosclerotic plaque in a vessel and for ablation of the plaque therein, the combination comprising:

a laser catheter including an actuating mechanism therefore;

first means responsive to an aspect representative of repetitive vessel movements for defining a time period cycle representative thereof and for dividing the time period cycle into a variable number of fixed times or time intervals;

second means responsive to the relative positions of the laser catheter and the plaque in the vessel for identifying those times or time intervals during a cycle (or a cardiac cycle) when the laser catheter is aimed at the plaque and those times or time intervals when it is not, and

computer means responsive to said first means and said second means for controlling the actuation of the laser catheter during at least one time or time interval of an upcoming cardiac cycle in which the laser catheter is oriented to the plaque.

8. The combination of Claim 7 in which the aspect representative of repetitive vessel movement relates to the cardiac cycle.

9. The combination of claim 7 wherein the first means includes electrocardiographic data and further includes associated means for defining a time period represented by the electrocardiogram QRS complex generated thereby and for defining a plurality of times therebetween.

10. The combination of claim 7 wherein the second means includes image acquisition and processing means for visually displaying on a CRT images of the vessel toward which the catheter is oriented and orientation of the catheter or its aiming mechanism relative to a target area.

11. The combination of claim 10 wherein the second means includes angiography imaging means.

12. The combination of claim 10 wherein the second means includes angioscopic imaging means.

13. The combination of claim 7 wherein the second means includes signal generating means and sensing means for sensing when the catheter is oriented toward the plaque in the vessel.

14. The combination of claim 13 wherein the second means includes a laser induced fluorescent signal.

4,788,975

7

15. The combination of claim 13 wherein the second means includes ultrasound signal means.

16. The combination of claim 7 wherein the first and second means generate electrical output signals representative of time and positional data, respectively.

17. The combination of claim 16 wherein the computer means is electronically connected to the first and second means and includes electronic data storage and display means for storing and displaying the time and positional data at operator command.

18. The combination of claim 17 wherein the computer means further includes manual data entry means for selecting certain times or time intervals during which the catheter is oriented toward plaque in the vessel.

19. The combination of claim 18 further including means for automatically triggering the firing of the laser catheter during the selected time intervals during an upcoming cycle or cycles.

20. The combination of claim 18 including means for deactivating the laser catheter.

21. In combination with a medical treatment device in which a treatment means is positioned within a moving body and oriented toward a selected site therewithin for effecting treatment thereof, the improvement comprising:

means for defining a repetitive time cycle representative of body movement;

means for defining the position of the treatment means relative to the selected site during various times of the time cycle, and

means for activating the treatment means at a selected time or times to effect treatment of the selected site.

22. In combination with a medical treatment system for effecting treatment to a selected site in a body or body part, the combination comprising:

medical treatment means inserting into the body including an actuating mechanism therefore;

first means responsive to repetition body movements for defining a time period representative thereof and for dividing the time period into a variable number of fixed times;

second means responsive to the relative positions of the medical treatment means and the site in the body for identifying those times or time intervals during a time period when the treatment means is oriented toward the site and those times or time intervals when it is not, and

computer means responsive to said first means and said second means for controlling the actuation of the medical treatment means during at least one

8

time or time interval of a cycle in which it is oriented toward selected site during upcoming cycle.

23. A method of timing the actuation of a laser angioplasty catheter carried in a moving vessel to assure impingement of laser radiation upon atherosclerotic plaque rather than on the vessel wall, the method comprising:

inserting the catheter into a vessel and positioning it toward a target area therein;

establishing a repeating time cycle based on vessel movement, including discrete times within the cycle;

selecting those discrete times in the cycle during which the catheter aiming mechanism is aimed at the plaque, and

arranging for the actuation of the laser during at least one of those determined discrete times in an upcoming cycle.

24. The method of claim 23 in which the step of selecting those times when aiming is at the plaque includes the use of an image acquisition, storage and display systems.

25. The method of claim 23 in which the step of selecting those times when aiming is at the plaque includes the use of sensing means for providing data that indicates the orientation of the catheter relative to the plaque.

26. The method of claim 23 in which the step of arranging for actuation of the catheter includes the use of computer means for correlating the selecting step with the actuation of the laser.

27. The method of claim 23 wherein the selecting step includes data from a plurality of modalities, some associated with the catheter per se and some independent thereof.

28. A method of timing the actuation of a medical treatment system in which a medical treatment means is inserted into the body and to assure effecting treatment by the means to a selected site in the body, the method comprising:

inserting the medical treatment means into the body and positioning it toward a selected site therein;

establishing a repeating time cycle based on certain body movement, including discrete times within the cycle;

selecting those discrete times in the cycle during which the medical treatment means is oriented toward the site and

arranging for the actuation of the medical treatment means during at least one of those determined discrete times or time intervals during an upcoming cycle.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 4,788,975
DATED   : December 6, 1988
INVENTOR(S) : Leonid Shturman

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Col. 1, line 12, delete "4,650,024" and insert "4,654,024"

Col. 3, line 34, delete "in" and insert - "is"

Col. 4, line 18, delete "Manograph" and insert "Monograph"

Col. 4, line 20, delete "Sessons" and insert "Sessions"

Signed and Sealed this

Thirtieth Day of May, 1989

Attest:

DONALD J. QUIGG

Attesting Officer

Commissioner of Patents and Trademarks

[54] **CONTROL SYSTEM AND METHOD FOR IMPROVED LASER ANGIOPLASTY**

[75] Inventors: **Leonid Shturman**, Minnetonka; **Steven L. Jensen**, Coon Rapids, both of Minn.

[73] Assignee: **Trimedyne, Inc.**, Irvine, Calif.

Reexamination Request:
No. 90/004,942, Feb. 19, 1998

Reexamination Certificate for:

Patent No.:	**4,788,975**
Issued:	**Dec. 6, 1988**
Appl. No.:	**117,666**
Filed:	**Nov. 5, 1987**

Certificate of Correction issued May 13, 1989.

[51] **Int. Cl.[6]** **A61B 17/36**
[52] **U.S. Cl.** **606/7; 606/12**
[58] **Field of Search** 606/2, 7-15; 600/519-522, 600/527

[56] **References Cited**

PUBLICATIONS

Cornelis J. Slager et al., *Vaporization of Atherosclerotic Plaques by Spark Erosion*, J. Am. Coll. Cardiol., vol. 5, No. 6, Jun. 1985:1382–1386.

George S. Abela et al., *Laser Angioplasty with Angioscopic Guidance in Humans*, J. Am. Coll. Cardiol., vol. 8, No. 1, Jul. 1986:184–192.

Primary Examiner—Max Hindenburg

[57] **ABSTRACT**

A control system and method for laser angioplasty or laser ablation or welding of tissue in general, in which firing of a laser catheter is correlated with movement of a vessel or other body chamber carrying the laser cathe- ter, whereby the laser is fired only during those times its fiberoptic-delivered beam is aimed at plaque or other target in the vessel or chamber.
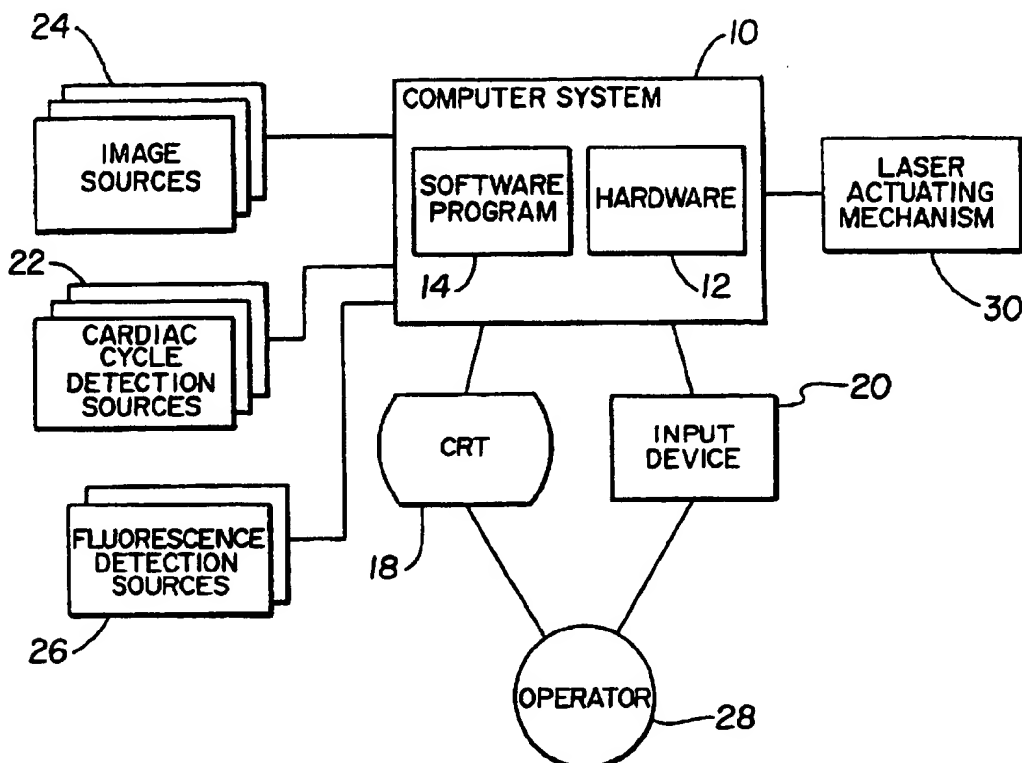
REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION. IT HAS BEEN DETERMINED THAT:

The patentability of claim(s) 1-28 is confirmed.

1. In combination with a laser angioplasty system in which a laser catheter is positioned within a moving vessel and oriented to impinge radiation upon a selected target site within the vessel, the improvement compris- ing:

means for defining a cycle representative of repetitive vessel movement;

means for defining the position of the laser catheter relative to the selected target site during various times of the cycle, and

means for activating the laser catheter at a selected time or times to impinge laser radiation on the target site during an upcoming cycle or cycles.

* * * * *

US006393091B1

(54) **METHODS AND APPARATUS FOR NON-UNIFORM TEMPORAL CARDIAC IMAGING**

(75) Inventors: **Christopher C. Slack; Jianying Li,** both of New Berlin, WI (US)

(73) Assignee: **General Electric Company,** Schenectady, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/460,261**

(22) Filed: **Dec. 13, 1999**

(51) Int. Cl.^{7} A61B 6/00; G01N 23/00; G21K 1/22; H05G 1/60

(52) U.S. Cl. 378/8; 378/95

(58) Field of Search 378/8, 95

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,952,201 A	4/1976	Hounsfield
4,182,311 A	1/1980	Seppi et al.
4,530,109 A	7/1985	Klausz
4,641,328 A	2/1987	Fujise
4,994,965 A	2/1991	Crawford et al.
5,533,085 A	7/1996	Sheehan et al.
5,544,212 A	8/1996	Heuscher
5,602,891 A	2/1997	Pearlman
5,751,782 A	5/1998	Yoshitome
5,832,051 A *	11/1998	Lutz 378/8
6,154,516 A	11/2000	Heuscher et al.
6,275,560 B1 *	8/2001	Blake et al. 378/8

FOREIGN PATENT DOCUMENTS

EP	0 370 341 A2	5/1990
EP	1 013 225 A1	6/2000
EP	1 050 272 A1	11/2000
EP	1 072 224 A2	1/2001
EP	1 088 517 A1	4/2001
EP	1 090 586 A2	4/2001
WO	WO 00/30539	6/2000

OTHER PUBLICATIONS

Woodhouse et al., "Coronary Arteries: Retrospective Cardiac Gating Technique to Reduce Cardiac Motion Artifact at Spiral CT," Radiology, Aug. 1997, pp. 566–569.

Spraggins et al., "Retrospective Cardiac Gating Requiring No Physiological Monitoring," undated, one page.

Broderick et al., "Measurement of Coronary Artery Calcium with Dual–Slice Helical CT Compared with Coronary Angiography: Evaluation of CT Scoring Methods, Interobserver Variations, and Reproducibility," AJR:167, Aug. 1996, pp. 439–444.

* cited by examiner

Primary Examiner—Robert H. Kim
Assistant Examiner—Courtney Thomas
(74) Attorney, Agent, or Firm—Carl B. Horton, Esq.; Armstrong Teasdale LLP

(57) **ABSTRACT**

A method for imaging a heart of a patient utilizing a CT imaging system includes steps of assigning a scanning priority to phases of a representative cardiac cycle of the patient's heart, selecting phases of the cardiac cycle for scanning in accordance with the assigned scanning priority, and obtaining image slices of the patient's heart corresponding the selected phases of the cardiac cycle. The method can be performed by a CT imaging system including an EKG machine to record EKG data.
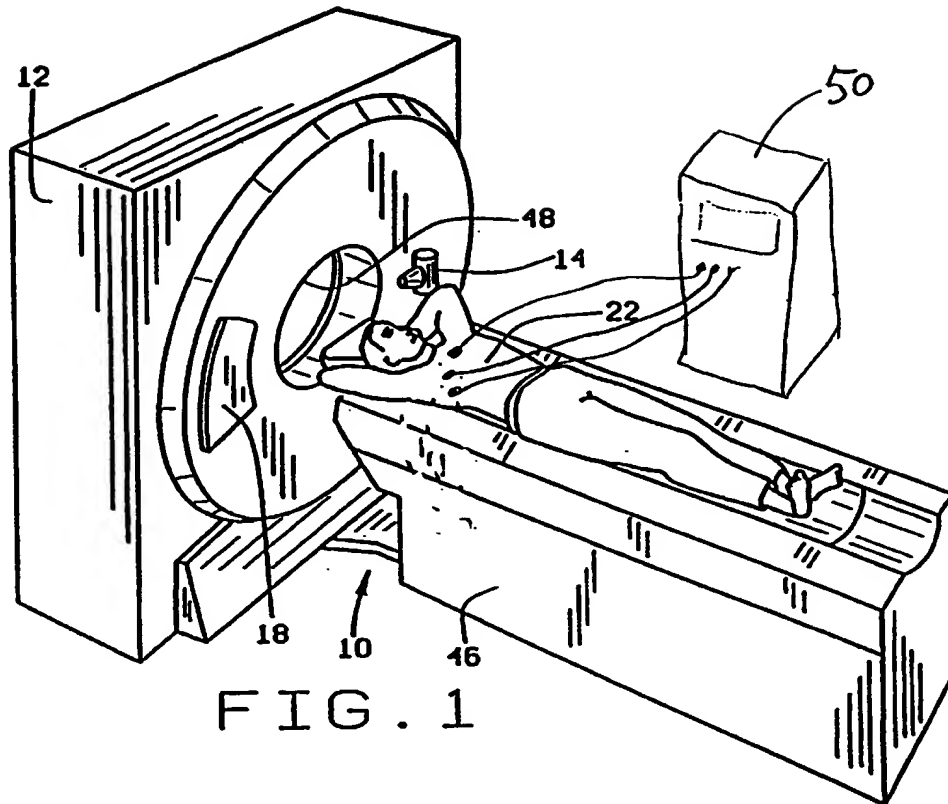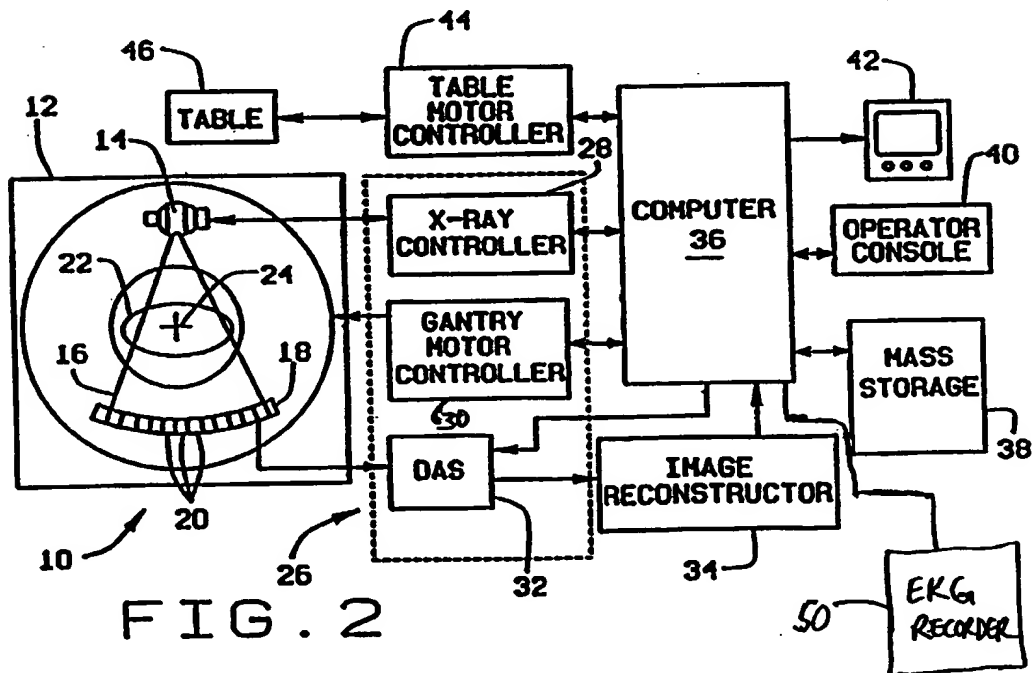
24 Claims, 2 Drawing Sheets
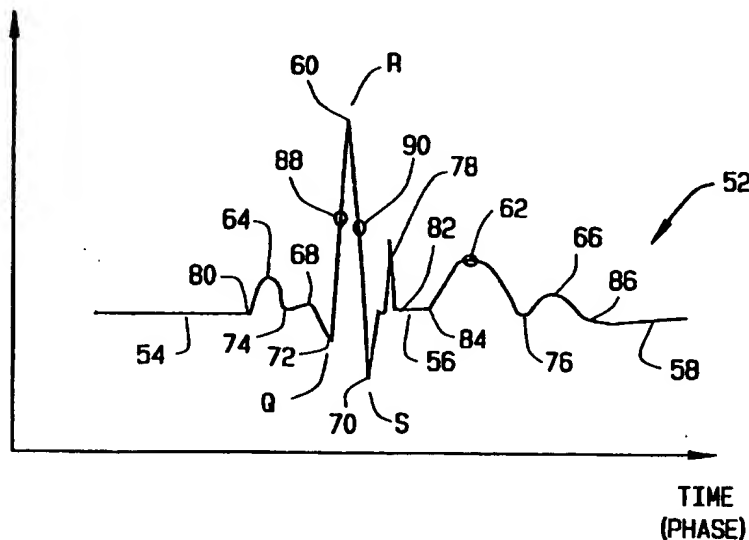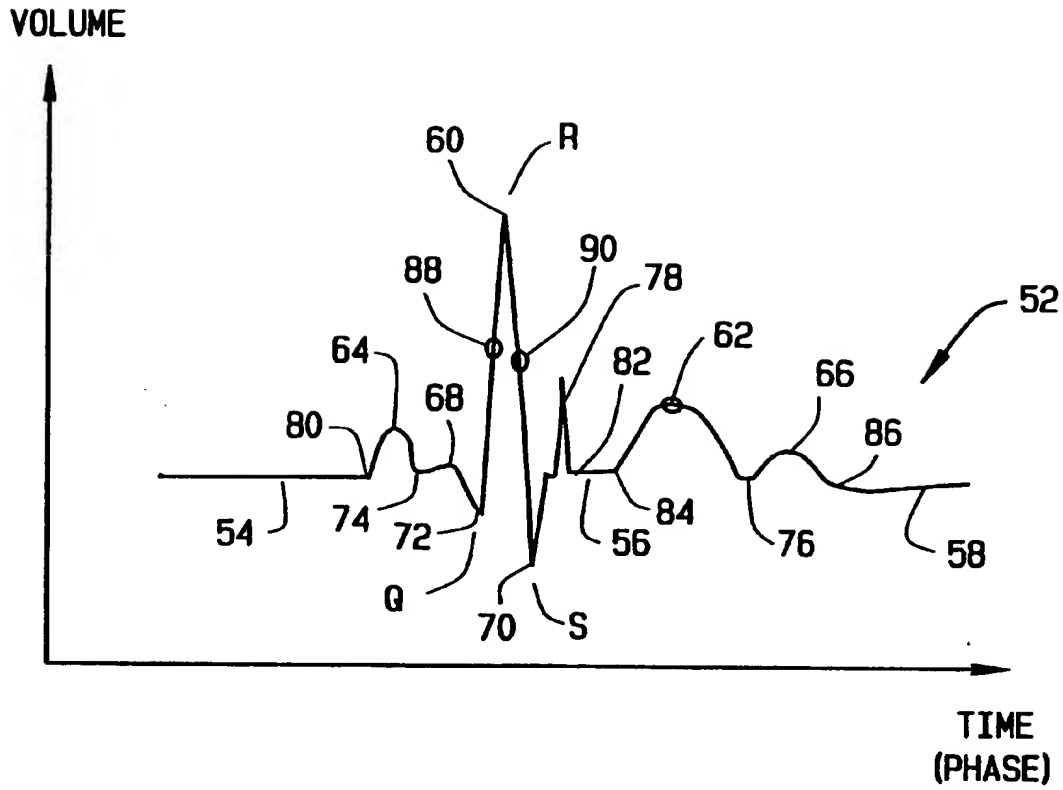
FIG. 1

FIG. 2

FIG.3

METHODS AND APPARATUS FOR NON-UNIFORM TEMPORAL CARDIAC IMAGING

BACKGROUND OF THE INVENTION

This invention relates generally to methods and apparatus for computed tomography cardiac imaging, and more particularly to methods and apparatus for non-uniform temporal recording of cardiac images.

In at least one known computed tomography (CT) imaging system configuration, an x-ray source projects a fan-shaped beam which is collimated to lie within an X-Y plane of a Cartesian coordinate system and generally referred to as the "imaging plane". The x-ray beam passes through the object being imaged, such as a patient. The beam, after being attenuated by the object, impinges upon an array of radiation detectors. The intensity of the attenuated beam radiation received at the detector array is dependent upon the attenuation of the x-ray beam by the object. Each detector element of the array produces a separate electrical signal that is a measurement of the beam attenuation at the detector location. The attenuation measurements from all the detectors are acquired separately to produce a transmission profile.

In known third generation CT systems, the x-ray source and the detector array are rotated with a gantry within the imaging plane and around the object to be imaged so that the angle at which the x-ray beam intersects the object constantly changes. A group of x-ray attenuation measurements, i.e., projection data, from the detector array at one gantry angle is referred to as a "view". A "scan" of the object comprises a set of views made at different gantry angles, or view angles, during one revolution of the x-ray source and detector. In an axial scan, the projection data is processed to construct an image that corresponds to a two dimensional slice taken through the object. One method for reconstructing an image from a set of projection data is referred to in the art as the filtered back projection technique. This process converts the attenuation measurements from a scan into integers called "CT numbers" or "Hounsfield units", which are used to control the brightness of a corresponding pixel on a cathode ray tube display.

Computed tomography images of the heart are useful for a number of diagnostic and surgical purposes. At least one known procedure requires that a collection of cardiac phase images be obtained. However, the process of obtaining such a collection is complicated by the fact that the heart does not beat in a uniform temporal fashion. During a single cardiac cycle, there are some times during which the volume of the heart is changing faster than average, and some times during which the volume changes more slowly than average. Currently, when temporal cardiac scanning is performed on a CT scanner, images corresponding to several phases of a cardiac cycle are captured at evenly spaced intervals. The images that are acquired are evenly spaced in time, resulting in an oversampling of certain phases of the cardiac cycle. Other phases are undersampled. Thus, temporal resolution is impaired. It would therefore be desirable for CT imaging apparatus and methods to optimize a collection of cardiac phase images by avoiding over- and undersampling.

BRIEF SUMMARY OF THE INVENTION

There is therefore provided, in one embodiment, a method for imaging a heart of a patient utilizing a CT imaging system including steps of assigning a scanning priority to phases of a representative cardiac cycle of the patient's heart, selecting phases of the cardiac cycle for scanning in accordance with the assigned scanning priority, and obtaining image slices of the patient's heart corresponding the selected phases of the cardiac cycle.

The above described embodiment results in a non-uniform temporal scan that provides improved temporal resolution. Moreover, both undersampling and oversampling of phases is avoided by the assignment of priorities, resulting in a more optimized collection of cardiac images.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a pictorial view of a CT imaging system.

FIG. 2 is a block schematic diagram of the system illustrated in FIG. 1.

FIG. 3 is a graphical representation of a cardiac cycle as a function of time.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIGS. 1 and 2, a computed tomograph (CT) imaging system 10 is shown as including a gantry 12 representative of a "third generation" CT scanner. Gantry 12 has an x-ray source 14 that projects a beam of x-rays 16 toward a detector array 18 on the opposite side of gantry 12. Detector array 18 is formed by detector elements 20 which together sense the projected x-rays that pass through an object 22, for example a medical patient. Detector array 18 may be fabricated in a single slice or multi-slice configuration. Each detector element 20 produces an electrical signal that represents the intensity of an impinging x-ray beam and hence the attenuation of the beam as it passes through patient 22. During a scan to acquire x-ray projection data, gantry 12 and the components mounted thereon rotate about a center of rotation 24.

Rotation of gantry 12 and the operation of x-ray source 14 are governed by a control mechanism 26 of CT system 10. Control mechanism 26 includes an x-ray controller 28 that provides power and timing signals to x-ray source 14 and a gantry motor controller 30 that controls the rotational speed and position of gantry 12. A data acquisition system (DAS) 32 in control mechanism 26 samples analog data from detector elements 20 and converts the data to digital signals for subsequent processing. An image reconstructor 34 receives sampled and digitized x-ray data from DAS 32 and performs high speed image reconstruction. The reconstructed image is applied as an input to a computer 36 which stores the image in a mass storage device 38.

Computer 36 also receives commands and scanning parameters from an operator via console 40 that has a keyboard. An associated cathode ray tube display 42 allows the operator to observe the reconstructed image and other data from computer 36. The operator supplied commands and parameters are used by computer 36 to provide control signals and information to DAS 32, x-ray controller 28 and gantry motor controller 30. In addition, computer 36 operates a table motor controller 44 which controls a motorized table 46 to position patient 22 in gantry 12. Particularly, table 46 moves portions of patient 22 through gantry opening 48 in a z-axis direction.

In one embodiment of the present invention, a non-uniform sampling technique is used to optimize temporal resolution of a collection of cardiac phase images. Sampling points are determined utilizing a signal representative of volumetric change of the heart, such as an EKG signal from EKG machine 50. Before scanning patient 22, data representing a typical cardiac cycle 52 of the heart of patient 22 is obtained utilizing EKG machine 50. For example, a

representative cardiac cycle 52 is computed from EKG signal data obtained from a plurality of normal cardiac cycles. The plurality of cycles are averaged to obtain the representative normal cycle, such as that illustrated in FIG. 3.

The representative cycle is analyzed for changes that occur at each phase in cardiac cycle 52. In particular, flat or baseline sections 54, 56, 58 are identified, as are local maxima 60, 62, 64, 66, 68 and minima 70, 72, 74, 76. Times at which local maxima 60, 62, 64, 66, 68 and minima 70, 72, 74, 76 occur relative to a reference time in cardiac cycle 52 are obtained by utilizing second derivative information from cardiac waveform 52. Voltages representing volume changes of the heart of patient 22 are produced by EKG machine 50. EKG cycle 52 thus determined represents volume changes of the heart. Rankings are assigned based upon a distance at each local maxima and minima from a baseline section 54, 55, 58 of waveform 52.

In one embodiment, data of representative cardiac cycle waveform 52 is filtered to reduce temporal and spatial noise. For example, cardiac cycle 52 is analyzed to determine volume changes and rates of change. Based on these determinations, a threshold is applied to cardiac waveform 52 to eliminate changes in the waveform that are small enough to be ignored. The threshold is selected by computing an estimated noise level or by estimating a noise level by visual inspection of waveform 52. Small volume changes in waveform 52 below the threshold are replaced with a flat baseline. For example, points 68, 74, and 76 are ignored. Short temporal impulses 78, such as those having shorter duration than a temporal resolution of CT imaging device 10, also are ignored. For example, impulses of duration less than about 100 ms are ignored. In another embodiment, thresholds are selected in accordance with a maximum desired temporal and spatial resolution. In one embodiment, thresholding is performed prior to locating maxima and minima of cardiac waveform 52.

After filtering waveform 52, all remaining local maxima 60, 62, 64, 66 and local minima 70, 72, 74 in a resulting waveform 52 are found. Each points 60, 62, 64, 66, 70, 72, 74 corresponds to different phases of representative cardiac cycle 52 of patient 22. Priority values are assigned to the phases of each of the local maxima 60, 62, 64, 66 and minima 70, 72, 74 in accordance with volume differences from baseline 54, 56, 58, the volume distances being represented by vertical distances in cardiac waveform 52. In one embodiment, greater volume differences are assigned greater priority. One such ordering of priority, in order from highest to lowest, is 60, 70, 62, 72, 64, and 66.

In one embodiment, at least one transition point 78, 80, 82, 84 or 86 on baseline 54, 56, 58 is also selected for scanning and imaging. Transition points 78, 80, 82, 84, and 86 occur at phases in which a volume change just begins to occur after a period of little or no motion. However, it is only necessary to scan at a single transition point, e.g., point 78, because the heart volume of patient 22 is approximately the same at each transition point 78, 80, 82, 84, and 86. A single imaging scan at the selected transition point is used to represent the heart at each of transition points 78, 80, 82, 84, 86. In one embodiment, a transition point is given a high priority above that of all maxima and minima.

In one embodiment, additional phases are assigned scanning priorities in accordance with temporal and spatial gradients. For example, phases 88 and 90 are selected between minima and maxima 72 and 60, and 60 and 70, respectively. Phases 88 and 90 or other such additional phases are selected when doing so is determined to be advantageous for reconstruction of images. Priority values are then assigned to the selected additional phases 88, 90. When there are fewer minima and maxima than phases, all minima and maxima phases are selected. Also, additional phases such as 88 and 90 are selected in order of priority (for example, those at which a magnitude of the slope of waveform 52 is greatest) until a total of the selected phases is equal to the number of sectors. On the other hand, when there are more minima and maxima than sectors, only the highest priority minima and maxima points are selected, up to a maximum number of available sectors. For example, only those minima and maxima having the greatest volume change as indicated by a vertical distance from baseline 54, 56, 58 are selected for scanning. More generally, phases are sorted in accordance with their assigned priority, and a number of points N of highest priority are selected, where N is a number of phases desired for generating images.

A cine cardiac scan (i.e., a scan during which gantry 12 rotates, but table 46 is held stationary) is then performed by CT imaging system 10 at a time interval corresponding to each of the N points along waveform 52. A reference phase from an EKG machine 50 sensing cardiac cycles of patient 22 is used, in one embodiment, to establish a reference for scanning times. For example, scanning times are referenced to occurrences of R peaks sensed by CT imaging system 10 in an EKG signal received from EKG machine 50.

An axial image slice is generated for each phase of a cine scan when CT imaging system 10 is a single-slice imaging system. When a collection of phases for more than one image plane or slice is desired, the cine scanning step is repeated for each plane or slice after table 46 is stepped to a new location. Collection of phases for more than one image plane or slice is further facilitated, in one embodiment, by utilizing a multi-slice imaging system as CT imaging system 10. Suitable adjustments are made in the stepping distance of table 46 in accordance with slice thicknesses and a number of slices collected simultaneously during a scan.

In one embodiment, N phases are not sufficient to include a desired temporal midpoint or phase, such as 88, during acquisition. In this embodiment, linear interpolations between phases preceding and following midpoint 88 are performed to fill in a temporal coverage gap in coverage. The newly interpolated slice is considered an additional phase for purposes of the invention.

Data is then displayed as image frames. As used herein, for a 2-D temporal display, a "frame" consists of a single scanned image. For a 3-D temporal display, a "frame" is a collection comprising a plurality of such images representing different image slices or planes. In the case of a 3-D temporal display, each image in the collection corresponds to the same phase in the patient's cardiac cycle. In one embodiment, a number of identical frames F to display for each phase P_n is written as:

$$F=(Pos(P_{n+1})-Pos(P_n))\times FR,$$

where:
F=a number of phases displayed for phase n;
P_n=phase n;
$Pos(P_n)$=a temporal position of phase n; and
FR=display frame rate.

With frames displayed in this manner, an animated display representing the heart of patient 22 is produced from an optimized collection of cardiac phase images. The resulting animated images have improved temporal resolution.

In one embodiment, CT imaging system 10 is programmed to perform steps described above. For example, computer 36 receives an EKG signal from EKG machine 50 for analysis. Software or firmware operating computer 36 averages an EKG waveform over a plurality of cycles and assigns scanning priorities in accordance with measurable characteristics of the average waveform. For example, software operating computer 36 assigns priorities strictly in accordance with computed second derivative values of a cardiac waveform to recognize maxima and minima, and also locates maximum and minimum slopes of the cardiac waveform. In addition, a baseline phase is also selected for scanning. Scanning is performed automatically by gating scan cycles with observed R-peaks of a cardiac cycle from an EKG taken during scanning. Image reconstructor 34 and/or computer 36 then compute images for display on CRT 42.

From the preceding description of various embodiments of the present invention, it is evident that CT cardiac images having improved temporal resolution are obtained by avoiding oversampling and undersampling of cardiac phases. Although particular embodiments of the invention have been described and illustrated in detail, it is to be clearly understood that the same is intended by way of illustration and example only and is not to be taken by way of limitation. In addition, the CT system described herein is a "third generation" system in which both the x-ray source and detector rotate with the gantry. Many other CT systems including "fourth generation" systems wherein the detector is a full-ring stationary detector and only the x-ray source rotates with the gantry, may be used if individual detector elements are corrected to provide substantially uniform responses to a given x-ray beam. Accordingly, the spirit and scope of the invention are to be limited only by the terms of the appended claims and legal equivalents.

What is claimed is:

1. A method for imaging a heart of a patient utilizing a CT imaging system, said method comprising the steps of:
assigning a scanning priority to phases of a representative cardiac cycle of the patient's heart in accordance with cardiac volume distances from a baseline volume;
selecting phases of the cardiac cycle for scanning in accordance with the assigned scanning priority; and
obtaining image slices of the patient's heart corresponding the selected phases of the cardiac cycle.

2. A method in accordance with claim 1 further comprising obtaining EKG data of the patient's heart, and wherein assigning a scanning priority in accordance with cardiac volume distances from a baseline volume comprises the step of assigning a priority to local maxima and minima of the heart volume in accordance with heart volumes indicated by the EKG data.

3. A method in accordance with claim 2 wherein obtaining EKG data of the patient's heart comprises the steps of recording a plurality of complete cardiac cycles of the patient's heart and computing the representative cardiac cycle of the patient's heart utilizing the plurality of complete cardiac cycles.

4. A method in accordance with claim 3 wherein computing the representative cardiac cycle comprises the step of averaging the plurality of complete cardiac cycles.

5. A method in accordance with claim 2 wherein obtaining image slices of the patient's heart comprises performing a cine scan of the patient's heart.

6. A method in accordance with claim 2 wherein assigning a scanning priority to phases of a representative cardiac cycle of the patient's heart comprises the step of assigning

a scanning priority in accordance with cardiac volume distances from a baseline volume and also in accordance with temporal and spatial gradients of the cardiac data.

7. A method in accordance with claim 6 further comprising the step of interpolating between at least a pair of selected phases to select an additional phase for scanning.

8. A method in accordance with claim 2 and further comprising the step of filtering the EKG data in accordance with criteria selected to reduce temporal and spatial noise.

9. A method in accordance with claim 2 wherein at least one of the selected phases is a phase corresponding to a baseline volume of the patient's heart.

10. A method in accordance with claim 1 and further comprising the step of displaying data as animated image frames, wherein a number of identical frames F to display for each phase P_n is written as:

$$F=(Pos(P_{n+1})-Pos(P_n))\times FR,$$

where:
F=a number of phases displayed for phase n;
P_n=a phase n;
$Pos(P_n)$=a temporal position of phase n; and
FR=a display frame rate.

11. A method in accordance with claim 10 wherein displaying data as animated image frames comprises the step of displaying frames consisting of one image slice.

12. A method in accordance with claim 10 wherein displaying data as animated image frames comprises the step of displaying frames comprising a plurality of image slices representing different planes at a single phase of the patient's cardiac cycle.

13. A CT imaging system for imaging a heart of a patient, said imaging system including a radiation source and detector configured to rotate in an imaging plane around the patient, the detector being configured to sense the projected x-rays that pass the heart of the patient, said imaging system configured to:
assign a scanning priority to phases of a representative cardiac cycle of the patient's heart in accordance with cardiac volume distances from a baseline volume;
select phases of the cardiac cycle for scanning in accordance with the assigned scanning priority; and
obtain image slices of the patient's heart corresponding the selected phases of the cardiac cycle.

14. A system in accordance with claim 13 further configured to obtain EKG data of the patient's heart, and wherein said system being configured to assign a scanning priority in accordance with cardiac volume distances from a baseline volume comprises said system being configured to assign a priority to local maxima and minima of the heart volume in accordance with heart volumes indicated by the EKG data.

15. A system in accordance with claim 14 wherein said system being configured to obtain EKG data of the patient's heart comprises said system being configured to record a plurality of complete cardiac cycles of the patient's heart and to compute the representative cardiac cycle of the patient's heart utilizing the plurality of complete cardiac cycles.

16. A system in accordance with claim 15 wherein said system being configured to compute the representative cardiac cycle comprises said system being configured to average the plurality of complete cardiac cycles.

17. A system in accordance with claim 14 wherein said system being configured to obtain image slices of the patient's heart comprises said system being configured to perform a cine scan of the patient's heart.

7

8

18. A system in accordance with claim 14 wherein said system being configured to assign a scanning priority to phases of a representative cardiac cycle of the patient's heart comprises said system being configured to assign a scanning priority in accordance with cardiac volume distances from a baseline volume and also in accordance with temporal and spatial gradients of the cardiac data.

19. A system in accordance with claim 18 further configured to interpolate between at least a pair of selected phases to select an additional phase for scanning.

20. A system in accordance with claim 14 configured to filter the EKG data in accordance with criteria selected to reduce temporal and spatial noise.

21. A system in accordance with claim 14 wherein at least one of the selected phases is a phase corresponding to a baseline volume of the patient's heart.

22. A system in accordance with claim 13 further configured to display data as animated image frames, wherein a number of identical frames F to display for each phase P_n is written as:

$$F = (\text{Pos}(P_{n+1}) - \text{Pos}(P_n)) \times FR,$$

where:

    F = a number of phases displayed for phase n;

    P_n = a phase n;

    $\text{Pos}(P_n)$ = a temporal position of phase n; and

    FR = a display frame rate.

23. A system in accordance with claim 22 wherein said system being configured to display data as animated image frames comprises said system being configured to display frames consisting of one image slice.

24. A system in accordance with claim 22 wherein said system being configured to display data as animated image frames comprises said system being configured to display frames comprising a plurality of image slices representing different planes at a single phase of the patient's cardiac cycle.

* * * * *

HPS Trailer Page
for
WEST

UserID: dmariam

Printer: cpk1_4c35_gbfvptr

Summary

Document	Pages	Printed	Missed	Copies
US006393091	7	7	0	1
Total (1)	7	7	0	-